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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,826	03/30/2004	Theoharis C. Theoharides	51275/148	3055

7590 07/30/2007

Law Offices of Dr Melvin Blecher
4329 Van Ness St, NW
Washington, DC 20016-5625

EXAMINER	
LEITH, PATRICIA A	
ART UNIT	**PAPER NUMBER**
1655	

MAIL DATE	DELIVERY MODE
07/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/811,826	THEOHARIDES, THEOHARIS C.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 40-45 are pending in the application and were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 40 and 42 are provisionally rejected on the ground of nonstatutory double patenting over claim 42 of copending Application No. 10/811,839, claims 14, 16, 18, 20, 25, 31 and 36 of copending Application No. 10/811,838, claims 14, 20, 25, 31 and 36 of copending application No. 10/610,909 and claims 14, 20, 25, 31 and 36 of copending application No. 10/439,301.

Claim 42 of 10/811,839 describes a composition comprising chondroitin sulfate, quercetin or myricetin, hydroxyzine and olive kernel extract (OKE) with the particular amounts of chondroitin sulfate and OKE as recited in Instant claim 42. Therefore, claim 42 of '839 'anticipates' claims 40 and 42 of the Instant application.

Claims 14, 16, 18, 20, 25, 31 and 36 of 10/811,838 describe a composition comprising chondroitin sulfate, quercetin or myricetin, hydroxyzine and OKE. Claim 32 of '838 for example, clearly discloses amounts of chondroitin sulfate and OKE which fall completely within the scope of the Instantly claimed amounts. Therefore, claims 14, 16, 18, 20, 25, 31 and 36 'anticipate' and claim 40 'makes obvious' claim 42 of the Instant application.

Claims 14, 20, 25, 31 and 36 of 10/610,909 describe a composition comprising chondroitin sulfate, quercetin or myricetin and hydroxyzine and OKE. Claim 36 specifically discloses the use of 200mg of chondroitin sulfate. Although none of the claims specifically recite the amount of OKE as Instantly claimed, varying amounts of components in pharmaceutical compositions was well known in the art. One of ordinary skill in the art would have been motivated to modify the proportions of active ingredients in the composition in order to enable the content of the preparation to be matched with the demands and needs of individuals which needed treatment. Such variations in amounts of pharmaceutically active ingredients is considered optimization of result effective variables, conventional practice in the art of pharmacology.

Claims 14, 20, 25, 31 and 36 of 10/439,301 describe a composition comprising chondroitin sulfate, quercetin or myricetin and hydroxyzine and OKE. Claims 25, 31 and 36 of '301 specifically recite amounts of OKE and chondroitin sulfate which overlap

or touch the ranges as Instantly claimed. Therefore, claims 14, 20, 25, 31 and 36 of 10/439,301 'anticipate' Instant claim 40 and 'make obvious' Instant claim 42.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Applicant's arguments were fully considered, but not found persuasive.

Applicant essentially argues that with regard to the rejection over claims 40 and 42 over application '839, 40 and 42 over application '838 and claims 40 and 42 over application '909, that the claims of '839, '838 and '909 which were used in the Double Patenting rejections were cancelled in preliminary amendments. However, Applicant is asked to review the record of each individual case. The claim numbers present in this rejection are pending in the stated applications as the claims in those cases were renumbered and are therefore still pending.

Pertaining to the rejection of claims 40 and 42 over application '301, Applicant argues that the claims of '301 recite more than just the constituents of the Instant claims. However, the application '301 is looked upon as if it is prior art against the Instant claims (while, it is not prior art, the analysis is similar with regard to Double patenting; whether or not the claims of the pending application makes obvious or

anticipates the Instantly claimed invention). Applicant is incorrect in the analysis of the Double Patenting rejection, and therefore, this rejection also remains standing.

Claim Rejections - 35 USC § 103

Claims 40-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ronca et al. (1998) in view of Scott et al. (1987) in view of Gelber et al. (US 6, 576, 267 B2) in view of Noblie et al. (US 4, 265, 823) (in light of Dr. Duke's Phytochemical and Ethnobotanical Database*) and in view of Weiner et al. (US 2002/0009448 A1).

This rejection is maintained for the reasons of record. Applicant's arguments were fully considered, but not found persuasive.

First, Applicant argues that "The combination of Nobile with Duke..olive kernel extract may contain the steroid estrol. The examiner is incorrect. First, Estrol per se is not a steroid; it is a nickname given to a large group of estrogens...Second, the examiner presents no evidence that an estrol or any steroid is present in olive kernel extract. Third, Duke mentions neither estrol nor olive kernels" (p. 4, Remarks). However, the examiner respectfully disagrees with Applicant. The term 'olive kernel extract' is given its broadest interpretation within reason. Limitations from the Specification are not read into the claimed invention. To reiterate from the previous

Office Action, the term 'olive kernel extract' is broad enough to read on a single compound extractable from olive kernel. Further, while Applicant argues that Duke does not teach estrole or olive kernels, it is clear that Duke teaches that estrole is found in the seed, or 'kernel' of the olive. Applicant attempts to negate the prior art by alleging that "estrol [sic, estrole] is not a steroid" however, has provided no scientific evidence of such in rebuttal. It is again reiderated that Duke was cited merely to relay that estrole is found in the seed of olives, and that the reference by Nobilie is not necessarily needed in this rejection because the claims state 'optionally comprising' olive kernel extract.

Applicant further argues that "..the references cited do not suggest such combinations....examiner is obliged to show by reference to specific evidence in the cited references that there was (i) a suggestion to make...and (ii) a reasonable expectation...Both the suggestion and reasonable expectation must be found within the prior art, and not be gleaned from applicants' disclosure (*In re Vaeck*) (p. 4, Remarks).

It is deemed that the prior art intrinsically suggested the combination of the individual constituents since each was known in the art for treating inflammation. Accordingly, each reference is analogous art, and each reference was available to the ordinary artisan at the time the invention was made. The combination of elements which were known for treating the same ailments is *prima facie* obvious lacking evidence of an unexpected result, or lacking specific non-obvious additional embodiments such as particular amounts which were not disclosed or suggested by the

prior art. One of ordinary skill in the art would have had a good expectation that the combination of elements would have provided for an additive effect on treating inflammation because all of the individual components were all known for this purpose.

Applicant cites Custom Accessories Inc. v. Jeffrey-Allen Industries: "Casting an invention ...not by the whole" (p. 5, Remarks). However, this case appears to be directed toward an apparatus and is not considered relevant to the claimed invention which is directed toward biological material. Again, the combination would have been obvious to one of ordinary skill in the art at the time the invention was made because each component in the composition/kit was known for treatment of inflammation.

Applicant cites U.S. v. Adams: "The attainment of surprising results or properties is a powerful demonstration of patentability" and offers that "...olive kernel extract both as an antioxidant and absorption promoter...are evidence that applicant has demonstrated surprising results, which further establishes patentability, which must be accepted by the examiner" (*In re Soni*) (p. 5, Remarks). However, properties of the olive kernel extract as found in the Specification is immaterial in that again, limitations from the Specification are not read into the claims. Further, the olive kernel extract is not even required by the claims, as the claims state that the olive kernel extract is only 'optionally added.'

Applicant argues that a case of obviousness may be overcome by showing that; "(I) the combination is improper....(II) objective indicia of patentability...or (III) secondary considerations exist" (p. 5, Remarks). Applicant additionally argues that "...the commercial success of the present invention was demonstrated in the Petition To Make Special previously filed" (again, p. 5, Remarks). However, Applicant bears the burden of submitting convincing evidence of commercial success. This evidence is not of record, and therefore, Applicant's argument is without merit. Further, the prosecution of record in this Application fails to indicate that Applicant has filed a petition to make special.

No Claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

July 12, 2007